

Remarks

Claims 45-65 were pending in the subject application. By this Amendment, claims 45, 50, 55, and 60 have been amended and new claims 70-77 have been added. The undersigned avers that no new matter is introduced by this Amendment. Support for the new claims and amendments can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Claim 65 remains pending but withdrawn from consideration. Accordingly, claims 45-64 and 70-77 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

Applicants acknowledge that claim 65 has been withdrawn from further consideration as being drawn to a non-elected invention. However, Applicants wish to reserve the right to rejoiner of the non-elected process claims upon an indication of an allowable product claim in accordance with MPEP §821.04.

Applicants and Applicants' representative wish to thank Examiner Lakia Tongue and Examiner Vanessa Ford for the courtesy of the telephonic interviews conducted with the undersigned on September 8, 2010 and October 6, 2010, regarding the rejections under 35 USC §112, first paragraph, and 35 USC §§102(a) and (b). The remarks and amendments set forth herein are consistent with the substance of the interviews and are believed to address the outstanding issues as discussed during the interview.

Submitted herewith is a Request for Continued Examination (RCE) under 37 CFR §1.114 for the subject application.

By this Amendment, Applicants have amended claims 45, 50, 55, and 60, and added claims 70-77. Support for the amendments to claims 45, 50, 55, and 60 can be found, for example, in Table 2 at pages 56-99 of the specification as filed, corresponding to paragraph [0199] of the application as published. Support for new claims 70-77 can be found, for example, at pages Table 2 at pages 56-99 and paragraph [0095] at page 41 of the specification as filed.

Claims 45-50, 52-60, and 62-64 are rejected under 35 USC §112, first paragraph, as lacking sufficient written description. The Examiner acknowledges that the specification provides a

sufficient written description of an isolated or purified polynucleotide, which encodes a polypeptide comprising SEQ ID NO:1. However, the Examiner asserts that the specification does not provide an adequate written description of the claimed Human Leukocyte Antigen (HLA) binding fragment. By this Amendment, Applicants have amended claims 45, 50, 55, and 60 to recite that the Human Leukocyte Antigen (HLA) binding fragment comprises an amino acid sequence selected from Lys-Thr-Asn-Lys-Trp-Glu-Asp-Ile-Tyr (SEQ ID NO:28), Lys-Ser-Ile-Tyr-Ile-Phe-Tyr-Thr-Tyr (SEQ ID NO:29), Gly-Thr-Phe-Thr-Phe-Gln-Asn-Met-Tyr (SEQ ID NO:30), Tyr-Phe-Glu-Cys-Ile-Met-Lys-Leu-Tyr (SEQ ID NO:32), Val-Tyr-Glu-Gly-Lys-Leu-Lys-Lys-Tyr (SEQ ID NO:33), Val-Val-Asp-Leu-Phe-Cys-Gly-Val-Gly-Tyr (SEQ ID NO:34), Phe-Ser-Ser-Ile-Asn-Thr-Tyr-Asp-Tyr (SEQ ID NO:35), Val-Ser-Asn-Val-Glu-Asp-Ser-Asn-Tyr (SEQ ID NO:36), or Asn-Ser-Asn-Tyr-Asn-Lys-Lys-Leu-Tyr (SEQ ID NO:37). These peptides are listed in Table 2 at pages 56-99 of the subject application as filed, corresponding to paragraph [0199] of the application as published. SEQ ID NOs: 28, 29, 30, 32, 33, 34, 35, 36, and 37 are fragments of SEQ ID NO:1 and correspond to the amino acid sequences of peptide numbers 98.0038, 98.0039, 98.0040, 98.0042, 98.0043, 98.0001, 98.0044, 98.0045, and 98.0046. As shown in Table 2, these peptides are chromosome 10 epitopes that bind both A*0101 and A*1101 and/or A*2402.

Applicants respectfully submit that the specification, which discloses each of the recited amino sequences, conveys with reasonable clarity to those of ordinary skill in the art that, as of the application's date, Applicants were in possession of the full genus of nucleic acids encoding each amino acid sequence (MPEP §2163). Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claims 45, 47, 50, 52, 55, 57, 60, and 62 are rejected under 35 USC §102(b) as anticipated by Hoffman *et al.* (WO 00/25728). The Office Action indicates that Hoffman *et al.* teach whole genes and the portions of the DNA that constitute protein-encoding genes, including SEQ ID NO:112, which is asserted to have five consecutive amino acids of SEQ ID NO:1. As indicated above, Applicants have amended claims 45, 50, 55, and 60.

To be anticipatory under 35 USC §102(b), a single prior art reference must disclose each and every element as set forth in the claim, either expressly or inherently. *Verdegaal Bros. v. Union Oil*

Co. of California, 814 F.2d 628, 631; 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants respectfully submit that Hoffman *et al.* do not teach a polynucleotide:

- a) encoding a polypeptide comprising SEQ ID NO: 1;
- b) encoding a Human Leukocyte Antigen (HLA) binding fragment of SEQ ID NO: 1, wherein said HLA binding fragment comprises an amino acid sequence selected from Lys-Thr-Asn-Lys-Trp-Glu-Asp-Ile-Tyr (SEQ ID NO:28), Lys-Ser-Ile-Tyr-Ile-Phe-Tyr-Thr-Tyr (SEQ ID NO:29), Gly-Thr-Phe-Thr-Phe-Gln-Asn-Met-Tyr (SEQ ID NO:30), Tyr-Phe-Glu-Cys-Ile-Met-Lys-Leu-Tyr (SEQ ID NO:32), Val-Tyr-Glu-Gly-Lys-Leu-Lys-Lys-Tyr (SEQ ID NO:33), Val-Val-Asp-Leu-Phe-Cys-Gly-Val-Gly-Tyr (SEQ ID NO:34), Phe-Ser-Ser-Ile-Asn-Thr-Tyr-Asp-Tyr (SEQ ID NO:35), Val-Ser-Asn-Val-Glu-Asp-Ser-Asn-Tyr (SEQ ID NO:36), or Asn-Ser-Asn-Tyr-Asn-Lys-Lys-Leu-Tyr (SEQ ID NO:37); or
- c) that is complementary along the full length of said polynucleotide of a) or b).

Accordingly, reconsideration and withdrawal of the rejection under 35 USC §102(b) is respectfully requested.

Claims 45, 47, 50, and 52 are rejected under 35 USC §102(a) as anticipated by Gardner *et al.* (*Nature*, 2002, 419:498-511). Applicants respectfully submit that the Patent Office has not met its burden to show that the relevant subject matter in the Gardener *et al.* reference was accessible to the public at the subject application's priority date. As discussed during the telephonic interviews, the STIC Search Alignment run on April 27, 2010, which was provided with the Office Action, indicates that the sequence in question was first incorporated into the UNIPROT/EMBL database on March 1, 2003 (*see* page 1, line 8: "DT 01-MAR-2003, integrated UniProtKB/TrEMBL"). Consequently, while the Gardner *et al.* reference published before the priority date of the subject application (December 6, 2002), the associated sequence does not appear to have been made publicly available until after the subject application's priority date.

As the Examiner is aware, "[t]he statutory language 'known or used by others in this country' (35 U.S.C. § 102(a)), means knowledge or use which is accessible to the public." *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); MPEP §2132. As the referenced sequence in the Gardner *et al.* reference was not accessible to the public before the application's priority date,

the sequence is not available as prior art under 35 USC §102(a). Accordingly, reconsideration and withdrawal of the rejection under 35 USC §102(a) is respectfully requested.

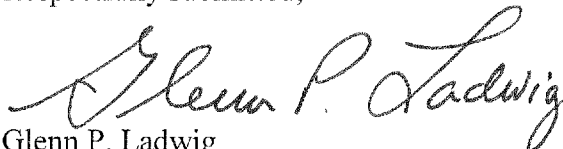
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachment: Request for Continued Examination